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(71) Applicant: KENSEY NASH CORPORATION [US/US]; Marsh Creek Corporate Center, Suite 204, 55 East Uwchlan Avenue, Exton, PA 19341 (US).

(72) Inventors: KENSEY, Kenneth; 8 Hickory Lane, Chester Springs, PA 19425 (US). NASH, John, E.; 145 Oak Street, Downingtown, PA 19335 (US).

(74) Agent: FAIGUS, Martin, L.; Caesar, Rivise, Bernstein, Cohen & Pokotilow, Ltd., 12th floor, Seven Penn Center, 1635 Market Street, Philadelphia, PA 19103-2212 (US).

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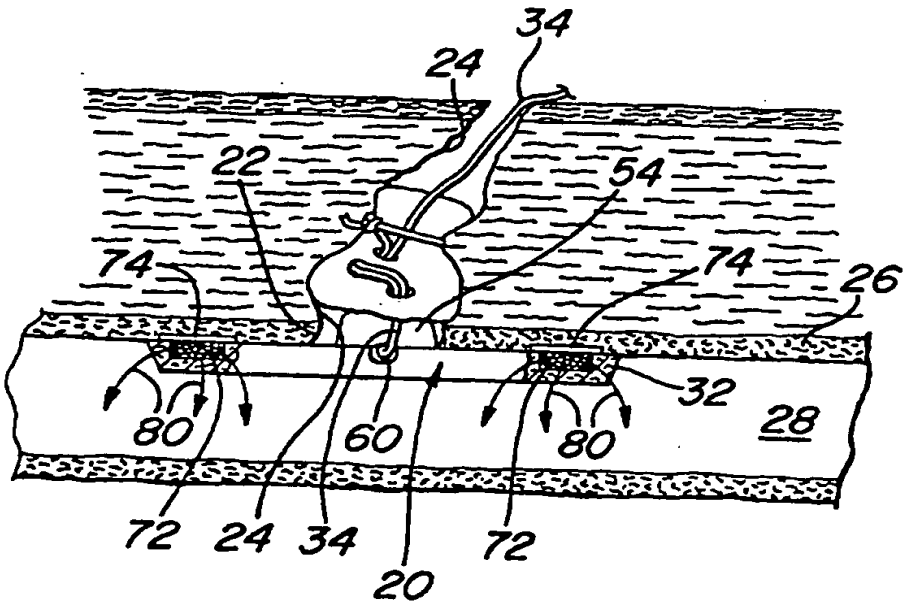
(54) Title: PERCUTANEOUS DRUG DOSING CLOSURE SYSTEM

(57) Abstract

A resorbable dispensing device (20, 20') for location in a percutaneous incision or puncture (22, 24) extending to an internally located penetratable organic structure within the body of a living being to provide at least a first biologically active material (72) for uptake by the body. The percutaneous incision or puncture includes an opening (22) in the tissue forming penetratable structure and a communicating tract (24) extending from the opening. The dispensing device can be used as a hemostatic closure and basically comprises anchoring means (32, 32', 32'', 32'''), sealing means (30, 30'), and positioning means (34), e.g., a filament. The anchoring means (32, 32', 32'', 32''') is introduced through the opening (22) onto one side of the penetratable structure to engage a portion of the tissue adjacent the opening to hold the anchoring means in place. The sealing means (30, 30') is arranged to be introduced into the tract (24) adjacent the anchoring means and to be positioned by the positioning means (34) on the other side of the tissue from the anchoring means to hold the entire device (20, 20') in position within the percutaneous incision or puncture (22, 24). The first biologically active material (72) is selected to have little or no significant clotting or anti-clotting effect on the blood of the being but has at least one significant physiological effect, e.g., therapeutic, diagnostic, or prophylactic, and is carried by at least one of the anchoring means (32, 32', 32'', 32''') and the sealing means (30, 30'). When used as a hemostatic closure the sealing means may carry a conventional blood clotting agent, e.g., tissue thromboplastin. If the anchoring means is located in a blood vessel it may carry a conventional non-thrombogenic material.



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PERCUTANEOUS DRUG DOSING CLOSURE SYSTEM

SPECIFICATION

This invention relates generally to medical devices and methods of use, and more specifically to a system and methods of use for applying medicines, drugs or other biologically active materials percutaneous into the body of a living being for uptake thereof.

BACKGROUND OF THE INVENTION

In our copending United States Patent Application Serial No. 07/846,322, filed on March 5, 1992, entitled Hemostatic Puncture Closure System and Method of Use, which is assigned to the same assignee as this invention and whose disclosure is incorporated by reference herein there is disclosed and claimed a system, a closure, and method of use for determining the position of a blood vessel via a percutaneous puncture and for sealing the percutaneous puncture in the blood vessel. In particular, the system includes an introducer sheath and associated positioning device, a hemostatic puncture closure, and a deployment instrument. The positioning device enables the introducer sheath to be positioned at a desired position within the vessel. The deployment instrument includes a tubular carrier storing the closure. The carrier has a distally located free end to be extended via an introducer through the puncture and its associated tract.

The closure comprises an anchor in the form of a radiopaque rigid member, a sealing member in the form of compressed collagen plug, and a thin filament connecting the two in a pulley-like arrangement. The carrier ejects the anchor through the introducer and puncture and then draws it against the free end of the introducer. The instrument and introducer are then withdrawn together to pull the anchor against the tissue contiguous with the incision or puncture in the artery wall on the inner surface thereof. Further withdrawal draws the plug out of the carrier into the puncture tract, whereupon the plug moves with respect to the anchor into position adjacent the outside of artery wall to seal the puncture or incision. A tensioning device limits the force applied to the filament. The carrier

also includes a tamper which is used to mechanically deform the plug within the tract. Once positioned hemostasis occurs rapidly, thereby locking the closure in place.

The system of that application constitutes an improvement upon earlier systems of the same assignee, such as those of United States Letters Patent No. 4,744,364 (Kensey), 4,852,568 (Kensey), 4,890,612 (Kensey), 5,021,059 (Kensey et al.), 5,061,274 (Kensey), and 5,222,974 (Kensey et al.), whose disclosures are also incorporated by reference herein.

In another of our copending United States Patent Applications, namely, Serial No. 08/012,816, filed on February 3, 1993, entitled A Hemostatic Vessel Puncture Closure System Utilizing A Plug Located Within The Puncture Tract Spaced From The Vessel, And Method Of Use, which is assigned to the same assignee as this invention and whose disclosure is incorporated by reference herein there is disclosed and claimed a system, making use of a closure having a spacer member located in the puncture tract interposed between the anchor and the sealing means but spaced from the opening in the wall of the blood vessel to ensure that if any portion of the sealing means should break off it will not enter into the blood vessel.

Notwithstanding the differences in the closures of all of the aforementioned patents and applications, all include portions which are arranged to be located within the interior of the a vessel duct or lumen, e.g., an artery, and portions which are to be located in the puncture tract, i.e., the passageway extending from the surface of the skin to the puncture or incision in the artery wall. In the later patents and patent applications the means located within the puncture tract comprises sealing means, e.g., a hemostatic plug, which is coupled to the anchor means located in the artery via filament means.

Where the type of closure utilized makes use of a sealing means located in the puncture tract hemostasis in that tract may be expedited by including a conventional clotting agent, e.g., tissue thromboplastin in the sealing means, and this fact has been disclosed in several of the aforementioned patents. Moreover, when the closure is used to seal a percutaneous

puncture in an artery the anchoring member, which is located within the interior of the artery, may be coated with a non-thrombogenic material to prevent the formation of blood clots (as also discussed in some of the aforementioned patents). In U.S. Patent No. 5,108,421 (Fowler) there is disclosed a vessel plug which may include a clotting agent or a radiopaque material. WIPO Publication No. WO 90/14796 (Van de Moer) discloses an occlusion element which contains agents to combat stenosis.

None of the aforementioned prior art discloses or suggests the use of a percutaneously inserted blood vessel puncture closure as a means of delivering some biologically active material have little or no significant clotting or anti-clotting effect on the blood of the being, but having at least one significant physiological effect, e.g., therapeutic, diagnostic, prophylactic.

Various skin-mounted or implantable devices have been disclosed in the patent literature and some are commercially available for dispensing one or more biologically active materials into the body of a living being. For example, U.S. Pat. No. 1,794,221 (Washburn et al.) discloses an applicator for applying a medicine-containing pad in the vagina. The pad remains in place and is removed by an attached string. U.S. Pat. No. 1,191,736 (Roberson) discloses an applicator for a tampon containing a medicament. U.S. Patent No. 4,356,572 (Guillemin et al.) discloses a biodegradable bone implant or prosthesis whose composition promotes bone growth but does not contain a separate drug. U.S. Pat. No. 4,606,337 (Zimmerman et al.) discloses a resorptive sheet material which promotes healing by providing a layer which is conductive to coagulation of blood using thrombin and fibrinogen. It can include layers containing active substances, i.e. antibiotics for gradual release. U.S. Patent No. 4,774,091 (Yamahira) discloses a solid bar-like or needle-like implantable sustained-release preparation consisting of an active ingredient and a biodegradable carrier.

While the aforementioned devices may be generally suitable for their intended purposes, they appear to leave much to be desired from one or more of various standpoints, e.g., ease of

placement, applicability to a wide variety of implant sites, simplicity of construction. Thus, a need exists for a drug delivery system which can provide a biologically active material, e.g., a drug, chemical, hormone, enzyme, antibody, percutaneously.

We have determined that the various closures of the aforementioned patents which have been disclosed above and which are assigned to the same assignee as this invention can serve as such drug delivery systems with very little modification thereof. In particular, the closures of the aforementioned patents and patent applications can be readily modified to render them particularly suitable for dispensing any type of biologically active material, e.g., therapeutic, diagnostic, prophylactic, into the body of the being for uptake thereby.

OBJECTS OF THE INVENTION

Accordingly, it is a general object of this invention to provide dispensing devices and methods of use which overcomes the disadvantages of the prior art.

It is another object of this invention to provide a dispensing device for location in a percutaneous incision or puncture in a living being to dispense a biologically active material therefrom for uptake by the being's body.

It is still another object of this invention to provide a resorbable dispensing device for location in a percutaneous incision or puncture in a living being to dispense a biologically active material therefrom for uptake by the being's body.

It is yet another object of this invention to provide a resorbable closure for sealing a percutaneous incision or puncture in a living being and for dispensing a biologically active material therefrom for uptake by the being's body.

It is yet another object of this invention to provide a dispensing device for location within a percutaneous incision or puncture in a living being to dispense a biologically active material therefrom, and which device is simple in construction, easy to use, and low in cost.

SUMMARY OF THE INVENTION

These and other objects of this invention are achieved by providing a resorbable dispensing device and method of use in a predetermined situs in a percutaneous incision or puncture extending to a blood vessel, duct, lumen, organ, or other penetratable organic structure within the body of a living being to provide at least a first biologically active material for uptake by some internal portion of the body to achieve a desired physiological effect. The percutaneous incision or puncture includes an opening in the tissue forming said vessel, duct, lumen, organ, or other penetratable structure and a communicating tract extending from the opening.

The dispensing device comprises anchoring means, sealing means, and positioning means. The anchoring means is arranged to be introduced through the opening onto one side of the tissue forming the vessel, duct, lumen, organ or other penetratable structure to engage a portion of that tissue adjacent the opening to hold the anchoring means in place with respect to the tissue. The sealing means is arranged to be introduced into the tract adjacent the anchoring means. The positioning means is coupled to the anchoring means and the sealing means and is operative to position the sealing means with respect to the anchoring means on the other side of the tissue from the anchoring means to hold the device in position.

The first biologically active material is selected to have little or no significant clotting or anti-clotting effect on the blood of said being but having at least one significant physiological effect, e.g., therapeutic, diagnostic, prophylactic. The first biologically active material is carried into the percutaneous incision or puncture by at least one of the anchoring means and the sealing means for release therefrom and uptake by said portion of said body to achieve a desired physiological effect.

In accordance with one aspect of this invention the dispensing device comprises a hemostatic closure, with the sealing means hemostatically sealing the puncture tract. In such an arrangement the sealing means may carry or include therein a

conventional blood clotting agent, e.g., tissue thromboplastin, to expedite hemostasis in the tract. If the closure is used with the anchoring means located in a blood vessel, e.g., an artery, the anchoring means may carry or include therein a conventional non-thrombogenic material.

The biologically active material can be of any desired formulation and can take any desired form, e.g., it may be a time release agent which is released from the device at a predetermined time after the device is in place within the percutaneous incision or puncture, or may be released from the device at a predetermined rate immediately upon placement within the percutaneous incision or puncture, or may be released from the device at a predetermined rate a predetermined time after the device is in place within the percutaneous incision or puncture.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and many of the attendant advantages of this invention will readily be appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

Fig. 1 is a top plan view of a dispensing closure device constructed in accordance with this invention shown with the sealing component in an uncompressed state;

Fig. 2 is a top plan view, like that of Fig. 1, but showing the sealing component in its compressed state ready for deployment into a percutaneous incision or puncture by an instrument like that disclosed in our aforementioned copending patent applications;

Fig. 3 is a side elevational view of the anchor component of dispensing closure device shown in Figs. 1 and 2;

Fig. 4 is a top plan view of the anchor component shown in Fig. 3;

Fig. 5 is an isometric view of an alternative anchor component constructed in accordance with this invention;

Fig. 6 is an enlarged side elevational view of the anchor component shown in Fig. 5;

Fig. 7 is an illustration, partially in section, showing the closure dispensing device of Figs. 1 - 4 located within a percutaneous incision or puncture in an artery for dispensing a biologically active material from the anchor component into the artery;

Fig. 8 is a side elevational view of another alternative anchor component constructed in accordance with this invention; and

Fig. 9 is an illustration, similar to Fig. 7, showing an alternative closure dispensing device located within a percutaneous incision or puncture in an artery for dispensing a biologically active material from the sealing component into the puncture tract; and

Fig. 10 is an isometric view of an alternative anchor component.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now in greater detail to the various figures of the drawings wherein like reference characters refer to like parts, there is shown at 20 a dispensing device constructed in accordance with this invention for location within a percutaneous incision or puncture extending from the skin to some penetratable structure located within the body of a living being in order to provide a biologically active material into that incision or puncture for uptake by the being's body. The percutaneous incision or puncture includes an opening 22 (Figs. 7 and 9) in the penetratable structure, e.g., a blood vessel, duct, lumen, organ, or other penetratable organic structure, and a communicating tract 24 or passageway extending from the opening 22 to the surface of the skin.

In the preferred embodiments shown herein in Figs. 7 and 9 the penetratable structure comprises an artery 26. The opening 22 extends through the wall of the artery so that it is in communication with the interior lumen 28 thereof and is also in communication with the puncture tract 24.

The construction of the dispensing device 20 and its various component parts will be described in considerable detail later. Suffice it for now to state that in the preferred embodiments

shown herein the device 20 is in the form of a closure similar to the closures of the aforementioned patents and patent applications. Thus, the dispensing closure includes a sealing portion (to be described later) for sealing the puncture tract from the egress of body fluids therefrom. To that end, and referring now to Figs. 1-4, it will be seen that the dispensing closure 20 has three basic components, namely, a sealing member 30, an intraarterial anchor member 32, and a positioning member 34.

The sealing member or plug 30 comprises a cylindrical member formed of a compressible, resorbable, collagen foam, such as that sold by Colla-Tec, Inc. of Plainsboro, NJ. and is arranged for sealing the puncture tract 24, and in some embodiments, e.g., Fig. 9, for delivering a biologically active material into the puncture tract.

The anchor member 32 is an elongated, stiff, low-profile, resorbable member which is arranged to be seated inside the penetrated internal structure against the tissue thereof contiguous with the opening through which it had been introduced to initially position the closure. The anchor member 32 is made of non-thrombogenic resorbable material, e.g., a resorbable polymer similar to a resorbable suture, such as a resorbable lactide/glycolide polymer sold by Medisorb Technologies International L.P. under the trade designation MEDISORB. The strip is sufficiently rigid such that once it is has been passed through the opening 22 in the penetratable structure, e.g., the artery 26, so that it is in its desired position it is resistant to deformation to preclude it from bending to pass back through the puncture opening through which it was first introduced.

The positioning member 34 preferably comprises a filament, e.g., a resorbable suture, which connects the anchor member 32 and the sealing member 30 (collagen plug) via a pulley-like arrangement. Accordingly, as shown clearly in Figs. 7 and 9 when the proximal end of the filament 34, which extends out of the puncture tract 24, is pulled in the proximal direction this action serves to move the plug member 30 toward the anchor 32 (which is engaging the interior surface of the artery contiguous

with the opening 22) through the puncture tract 24, close to but not into engagement with the exterior of the artery wall. In fact the sealing means abuts a domed portion of the anchor which extends into the opening 22. This action keeps the sealing member away from the artery, where a portion could conceivably break off and flow distally, but within the puncture tract 24 so that it can hemostatically seal that tract from the passage of fluid thereout.

The plug 30 is arranged to be compressed from the large diameter configuration shown in Fig. 1 to the small diameter, elongated configuration shown in Fig. 2. In the configuration of Fig. 2 the diameter of the plug is very small, e.g., 1.32 mm, and therefor suitable for disposition within the deployment instrument (not shown) for introducing it. That instrument is disclosed in the aforementioned patent applications Serial Nos. 07/846,322, filed on March 3, 1992, and 08/012,816, filed on February 3, 1993. The plug 30 includes an annular recess 40 extending about its outer periphery adjacent its proximal end. Three apertures 42, 44, and 46 extend through the plug. In particular, the aperture 42 is located close to the recess 40 and diametrically through the centerline of the plug. The aperture 46 is located close to the distal end of the plug and extends transversely through the plug on one side of the centerline. The aperture 44 is located between apertures 42 and 44 and extends transversely through the plug on the other side of the centerline. These apertures serve as passageways through which the filament 34 extends to connect the anchor member 32 to the plug member 30 and are spaced apart to preclude tearing of the plug.

The manner of connection of the plug member to the anchor member serves to couple the plug component to the anchor component in an arrangement to effect the movement of the plug component toward the anchor component, once the anchor component is in its desired position in the penetratable internal body structure, e.g., an artery, at the puncture or incision. In particular the coupling of the plug component to the anchor

component simulates a pulley to achieve a desired mechanical advantage.

The anchor member 32 has a generally planar top surface 48 (Fig. 3), a radially contoured bottom surface 50 and a peripheral side surface 52. Each end of the member 32 is rounded. The side surface 52 of the anchor member 32 tapers inward slightly from its top surface 48 to its bottom surface 50 to facilitate the removal of the plug from the mold for making it. A hemispherical dome-like projection 54 is located at the center of the top surface 48. The top surface of the dome 54 is slightly flatted.

A cylindrical opening 60 extends transversely across the member 32 under the domed projection 54. In particular the filament 34 is threaded through the cylindrical opening 60 to connect the plug member 30 to the anchor member 32. In this regard the pulley-like connection between the anchor member and the plug member is effected by threading the filament 34 from a remote point in a chamber (not shown) in the proximal portion of the deployment instrument through the transverse aperture 42, down the plug to the aperture 46, through that aperture to the opposite side of the plug and from there to the anchor member where it is threaded through the opening 60. From there the filament 34 extends back to the plug where it enters into aperture 44, passes through the aperture to the opposite side of the plug, where it terminates in a loop 66 extending around the annular recess 40. The loop is secured by a knot 68.

As can be seen clearly in Figs. 3 and 4, the anchor 32 includes two chambers or recesses 70 in the top surface 48 of the anchor adjacent each rounded end thereof. Each of these recesses is arranged to receive any suitable biologically active material 72 having at least one significant physiological, e.g., therapeutic, diagnostic, prophylactic, effect on the being. A third recess or chamber may be located in the flatted top of the domed portion 54 of the anchor 32' as shown in the embodiment of the anchor of Fig. 5. In any case, and as will be appreciated by those skilled in the art, the biologically active material 72 can take any suitable form, e.g., it may be a solid, a compressed powder or tablet, a particulate or powder, a liquid, or

microencapsulated spheres or pellets. In accordance with the embodiment shown in Figs. 1 - 7 the biologically active material 72 is held within each chamber 70 by a respective cover 74 of a thin film, e.g., the same material as that of the anchor, which is secured by heat or a solvent to the anchor member around the periphery of the associated recess.

In the embodiment of the anchor 32" shown in Fig. 8 the biologically active material 72 is dispersed throughout the material making up the anchor member, i.e., the anchor member is molded with the material 72 therein.

In Fig. 10 there is shown an alternative anchor component 32‴ constructed in accordance with this invention. That component 32‴ is similar to the components 32, 32′ and 32" described heretofore except for the asymmetrical shape of its ends, the flatted sides 54′ of the dome shaped portion 54, and the shape of the filament 34 receiving passageway or opening 50′.

In any case where the anchor material enclosing the biologically active material 72 is resorbable, the biologically active material will be released upon the resorption of the anchor member with the being's body for uptake thereby.

As should be appreciated by those skilled in the art depending upon the application desired the anchor member may be constructed and the biological material 72 chosen so that it will be released or gain egress from the anchor member immediately following the placement of the dispensing closure device 20 within the percutaneous incision or puncture or may be arranged to be released or gain egress therefrom a predetermined time after location within the patient's body. In fact, the release of the material 72 may be accomplished at once or over some period of time, be it protracted or short, and at a predetermined or controlled rate, irrespective of the time that the release begins. To achieve those ends the anchor member and/or the material 72 may be constructed in various ways which will be apparent to those skilled in the art.

As should be appreciated from the foregoing when the dispensing closure device 20 is constructed in accordance with the teachings of Figs. 1 - 7 and is used so that the anchor

member 32 is located within an artery 26, a duct, or other fluid carrying lumen, once the biologically active material 72 is released from the anchor, it may be carried by the fluid flowing through that lumen to immediately adjacent tissue or to tissue at remote locations.

In Fig. 9 there is shown an alternative embodiment of a dispensing closure device constructed in accordance with this invention for dispensing a biologically active material directly into the puncture tract 24, and from there, if desired through the opening 22 in the tissue of the penetratable structure into the structure itself, e.g., the artery. To achieve that end the dispensing closure device 20' of Fig. 9 is similar in construction to the device 20 of Fig. 7 except that the sealing member or plug 30' includes the biologically active material 72. In such a case the anchor member 32' need not contain the biologically active material 72 (although it could contain the same or another biologically active material, if desired). If no biologically active material is needed to be carried by the anchor member into the being's body the anchor member need not utilize any recesses 70. However, if desired the anchor can still make use of such recesses to hold a radiopaque material therein, such as disclosed in the aforementioned application 07/846,322, to facilitate fluoroscopic placement of the dispensing closure device 20. In fact, the recesses 70 in the anchor may be provided and left hollow, albeit covered with the covers 74, to create a pair of hollow spaces which may be readily visible using conventional imaging techniques.

The biologically active material 72 may be incorporated into the plug 30 in any suitable manner, e.g., as a coating on its surface(s), as microspheres or particulates entrapped within the plug material, e.g., as a collagen foam fibrillar matrix of the collagen making up the plug and the biologically active material 72, or in any other suitable manner which will be apparent to those skilled in the art.

The dispensing closure device 20 is used as follows: the physician inserts the delivery or deployment instrument (not shown) containing the device 20 into a conventional introducer

sheath (not shown) extending into the patient's body to the situs of the structure to be penetrated and dosed with the biologically active material. In the case where the biologically active material is to be introduced into a percutaneous incision or puncture extending into a artery the dosing procedure is as follows: the anchor member 32/32' is passed out of the distal end of the introducer sheath in the manner disclosed in our aforementioned applications so that it is deployed within the artery lumen. The deployment instrument is then withdrawn from the introducer sheath until resistance is felt when the anchor member catches on the distal end thereof. Once this occurs (and assuming that the anchor is in the correct orientation when it catches on the end of the introducer sheath the deployment instrument and the introducer sheath are then immediately withdrawn together. This withdrawing action causes the anchor member 32/32' to engage (catch) on the inner surface of the artery wall 26 contiguous with the puncture's opening 22. Continued withdrawal of the instrument and introducer sheath causes the pull-like configuration of the filament 34 to pull the collagen plug 30/30' toward the anchor member 32/32', thereby depositing the plug in the puncture tract 24 adjacent the exterior of the artery contiguous with the puncture. The plug 30/30' does not engage the arterial wall but rather it contacts the flatted domed portion 54 of the anchor member 32/32' which extends from the interior of the artery into and somewhat through the opening 22 in the artery wall (See Figs. 7 and 9). This action prevents the plug 30/30' from being pulled into the artery's interior. The pulling on the filament 34, to bring the sealing member or plug 30,30' into engagement with the anchor's dome 54, also has the effect of deforming the plug 30/30' into a larger diameter body to aid in holding it in place within the puncture tract 24 as shown in Figs. 7 and 9. Moreover, since the plug 30/30' is formed of compressed collagen or other hydrophilic material it also expands automatically in the presence of blood within the puncture tract 24 when deployed, thereby further contributing to the plug's enlargement. Further still, the deployment instrument includes a tamper (not shown)

which is mounted on the filament 34 and which is slidable thereon.

The deployment of the dispensing closure device 20 also effects the deployment of the tamper into the puncture tract 24 proximally of the plug 30/30'. The tamper is then used to gently compress and lock the collagen plug 30/30' on the suture filament 34 within the puncture tract 24, but outside of the artery. The closure 20 is now locked in place through the clotting of the hemostatic collagen plug and by spring tension provided by spring means (not shown) and forming a portion of the deployment system located on the filament 34.

Immediately after placement the anchor 32 starts to absorb water and to break down by hydrolysis. The process of encapsulation of the anchor by the arterial wall also commences. After approximately thirty days, only a small deposit of anchor material will remain. In fact, resorption of all components will have occurred after approximately sixty days.

When the dispensing closure device 20 is constructed like the embodiment shown in Fig. 7 and is located within the percutaneous incision or puncture as shown, upon the resorption of the anchor member 32/32'/32" itself or of the material 74 forming the chamber cover 74 the biologically active material 72 gains egress from the anchor and is picked up by the blood as shown graphically by the arrows designated with the reference number 80. The biologically active material is then taken up by the patient's body. When the dispensing closure device 20 is constructed like the embodiment shown in Fig. 9 and is located within the percutaneous incision or puncture as shown the biologically active material 72 in the sealing plug 30' gains egress from the sealing plug and is picked up by the blood or other fluid in the tissue contiguous with the puncture tract 24 as shown graphically by the arrows designated with the reference number 82. Depending upon the composition of the material 72 some of it may flow through the opening 22 into the interior of the artery for uptake by a remote portion of the patient's body.

If desired a spacer member (not shown), like that disclosed and claimed in our aforementioned copending application S.N.

08/012,816 may be utilized interposed between the anchor member 32 and the sealing or plug member 30 to further space the plug member from the artery. The spacer member may, if desired, be constructed, to include any type of biologically active material 72 therein. In such a case the spacer member will also serve to deliver that biological material into the puncture tract 24 for uptake by the body.

Without further elaboration the foregoing will so fully illustrate our invention that others may, by applying current or future knowledge, adopt the same for use under various conditions of service.

CLAIMS

What is claimed is:

1. A resorbable dispensing device (20, 20') for location at a predetermined situs in a percutaneous incision or puncture (22, 24) extending to a blood vessel, duct, lumen, organ, or other penetratable organic structure within the body of a living being to provide at least a first biologically active material (72) at said situs for uptake by some internal portion of the body of said being to achieve a desired physiological effect, said percutaneous incision or puncture including an opening (22) in the tissue forming said vessel, duct, lumen, organ or other penetratable structure and a communicating tract (24) extending from said opening, characterized in that said device (30) comprises anchoring means (32, 32', 32", 32'"), sealing means 30, 30'), and positioning means (34), said anchoring means (32, 32', 32", 32'") being arranged to be introduced through said opening (22) onto one side of the tissue forming said vessel, duct, lumen, organ or other penetratable structure to engage a portion of said tissue adjacent said opening to hold said anchoring means in place with respect to said tissue, said sealing means (30, 30') being arranged to be introduced into said tract (24) adjacent said anchoring means (32, 32', 32", 32'"), said positioning means (34) being coupled to said anchoring means (32, 32', 32", 32'") and said sealing means (30, 30') and being operative to position said sealing means with respect to said anchoring means on the other side of said tissue from said anchoring means to hold said device in position, said first biologically active material (72) being selected to have little or no significant clotting or anti-clotting effect on the blood of said being but having at least one significant physiological effect, said first biologically active material being carried by at least one of said anchor means (32, 32', 32", 32'") and said sealing means (30) for release therefrom and uptake by said portion of said body to achieve a desired physiological effect.

2. The device (20, 20') of Claim 1 characterized in that said biologically active material (72) is selected so that said physiological effect is therapeutic.

3. The device (20, 20′) of Claim 1 characterized in that said biologically active material (72) is selected so that said physiologic effect is diagnostic.

4. The device (20, 20′) of Claim 1 characterized in that said biologically active material (72) is selected so that said physiological effect is prophylactic.

5. The device (20, 20′) of Claim 1 characterized in that said biologically active material (72) is in time release form.

6. The device (20, 20′) of Claim 5 characterized in that said biologically active material (72) is released from said device at a predetermined time after said device is in place.

7. The device (20, 20′) of Claim 5 characterized in that said biologically active material (72) is released from said device at a predetermined rate.

8. The device (20, 20′) of Claim 6 characterized in that said biologically active material (72) is released from said device at a predetermined rate.

9. The device (20, 20′) of Claim 1 characterized in that said device comprises a closure wherein said sealing means (30, 30′) hemostatically seals said puncture tract from the egress of fluid therefrom.

10. The device (20′) of Claim 9 characterized in that said sealing means (30′) carries a second biologically active material in the form of a conventional blood clotting agent.

11. The device (20, 20′) of Claim 9 characterized in that said anchoring means (32, 32′, 32″, 32‴) comprises a second biologically active material (72) in the form of a non-thrombogenic material.

12. The device (20′) of Claim 10 characterized in that said anchoring means (32′) comprises a third biologically active material (72) in the form of a non-thrombogenic material.

13. A method of using a resorbable device (20, 20′) including an anchoring means (32, 32′, 32", 32‴), a sealing means (30, 30′), and a positioning means (34) to provide at least a first biologically active material (72) into a vessel, duct, lumen, organ, or penetratable structure within the body of a living being by inserting the device (20, 20′) into a predetermined situs in a percutaneous incision or puncture (22, 24) in the body of a living being, said percutaneous incision or puncture including an opening (22) in the tissue forming a vessel, duct, lumen, organ, or structure, in the body of the being, and a tract (24) extending from said opening to the surface of the skin of the being, characterized in that said method comprises the steps of providing said first biologically active material (72) for transportation into said percutaneous incision or puncture by said device, said first biologically active material (72) being selected to have little or no significant clotting or anti-clotting effect on the blood of said being but having at least one significant physiological effect, introducing said anchor means (32, 32′, 32", 32‴) through said opening (22) into the interior of the vessel, duct, lumen, organ, or penetratable structure to engage a portion of the tissue thereof adjacent said opening, introducing said sealing means (30, 30′) into said tract (24), coupling said positioning means (34) between said anchoring means and said sealing means and operating said positioning means to cause said sealing means to position said sealing means at a desired position with respect to said anchoring means and whereupon said sealing means engages tissue contiguous with said tract, said first biologically active material being released from said device for uptake by some internal portion of the body of said being after location at said situs.

14. The method of using the resorbable device (20, 20′) as set forth in Claim 13 characterized in that said step of introducing said sealing means (30, 30′) is carried out to hemostatically seal said tract (24) from the egress of liquid therefrom.

15. The method of using the resorbable device (20') as set forth in Claim 14 additionally characterized by providing said sealing means (30') with a second biologically active material in the form of a conventional blood clotting agent to be carried by said sealing means (30') into said tract (24).

16. The method of using the resorbable device (20, 20') as set forth in Claim 14 additionally characterized by providing said anchoring means (32, 32', 32", 32"') with a second biologically active material (72) in the form of a non-thrombogenic material to be carried by said anchoring means into said vessel, duct, lumen, organ, or penetratable structure.

17. The method of using the resorbable device (20, 20') as set forth in Claim 15 additionally characterized by providing said anchoring means (32, 32', 32", 32"') with a third biologically active material (72) in the form of a non-thrombogenic material to be carried by said anchoring means into said vessel, duct, lumen, organ, or penetratable structure.

18. The method of using a resorbable device (20,20'), as set forth in Claim 13 characterized by releasing said first biologically active material to provide a therapeutic effect.

19. The method of using a resorbable device (20,20'), as set forth in Claim 13 characterized by releasing said first biologically active material to provide a diagnostic effect.

20. The method of using a resorbable device (20,20'), as set forth in Claim 13 characterized by releasing said first biologically active material to provide a prophylactic effect.

21. The method of using a resorbable device (20,20'), as set forth in Claim 13 characterized by providing said first biologically active material in time release form.

22. The method of using a resorbable device (20,20'), as set forth in Claim 13 characterized by releasing said first biologically active material from said device at a predetermined time after said device is in place.

23. The method of using a resorbable device (20,20'), as set forth in Claim 13 characterized by releasing said first biologically active material from said device at a predetermined rate.

24. The method of using a resorbable device (20,20'), as set forth in Claim 22 characterized by releasing said first biologically active material from said device at a predetermined rate.

FIG. 1

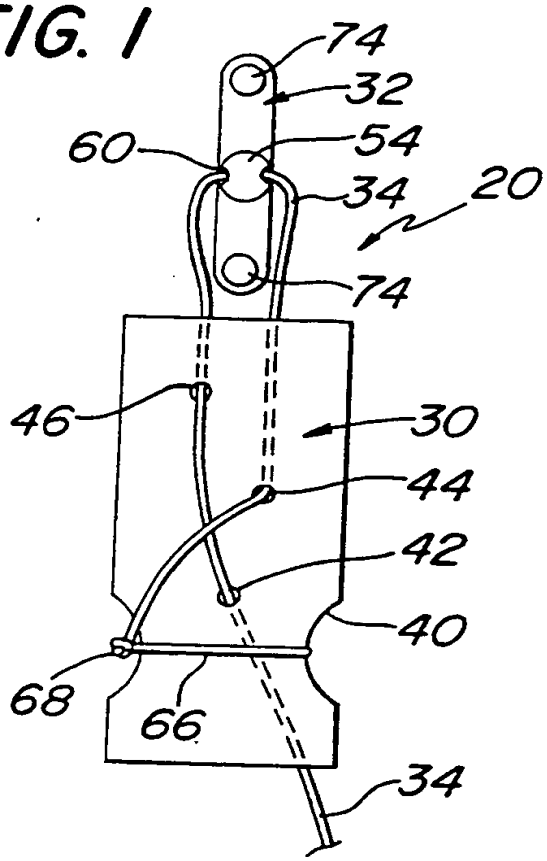


FIG. 2

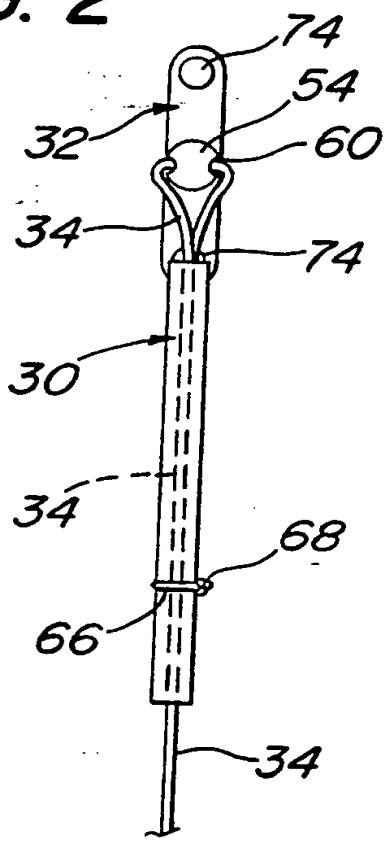


FIG. 3

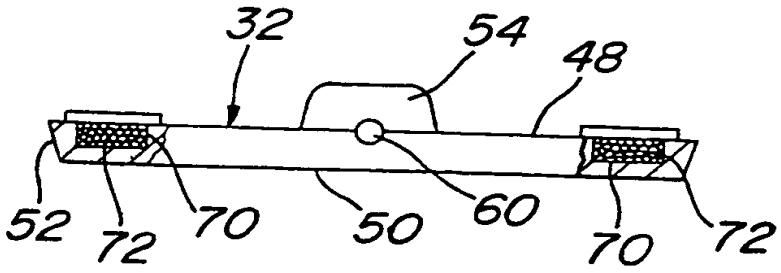


FIG. 4

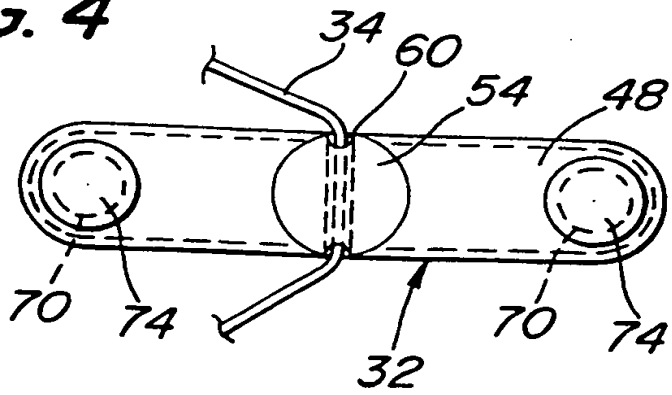


FIG. 5

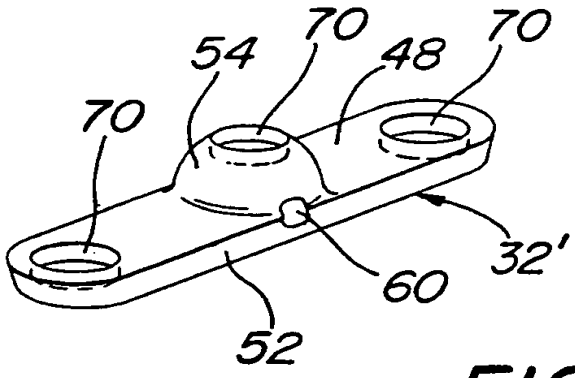


FIG. 6

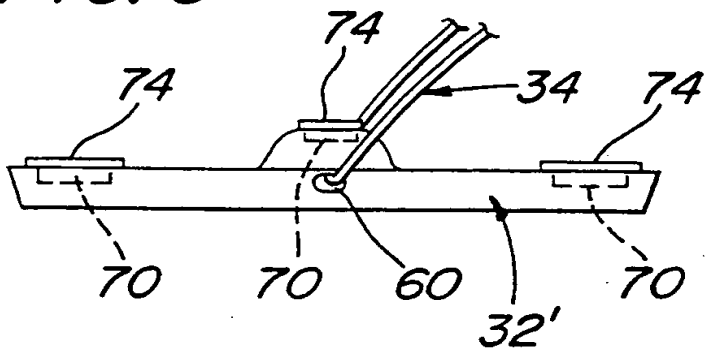


FIG. 7

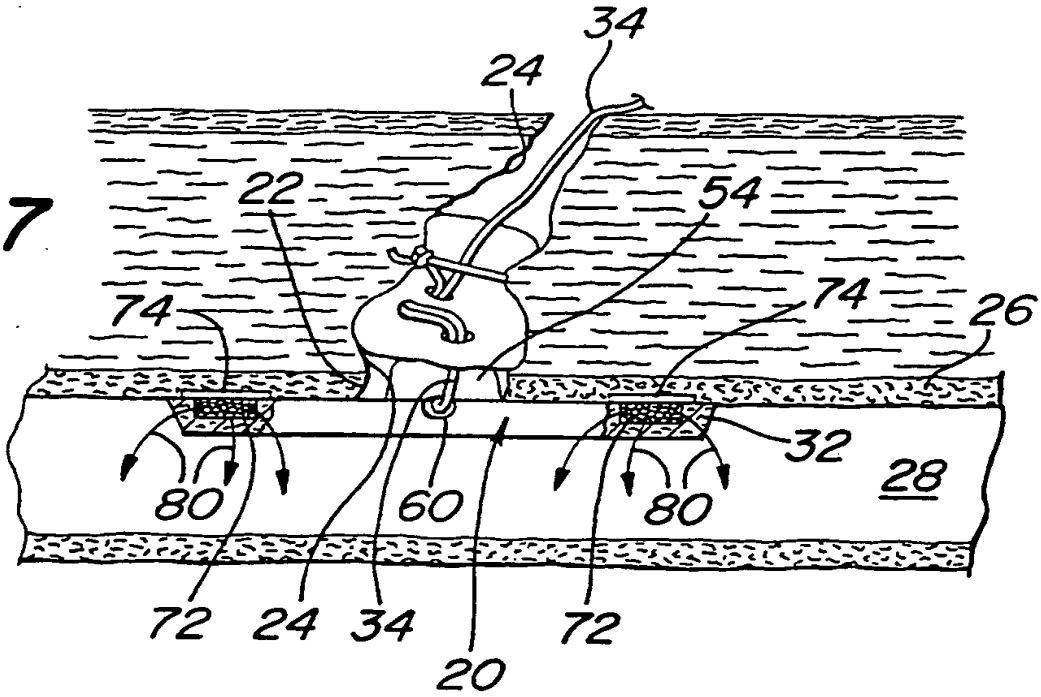


FIG. 8

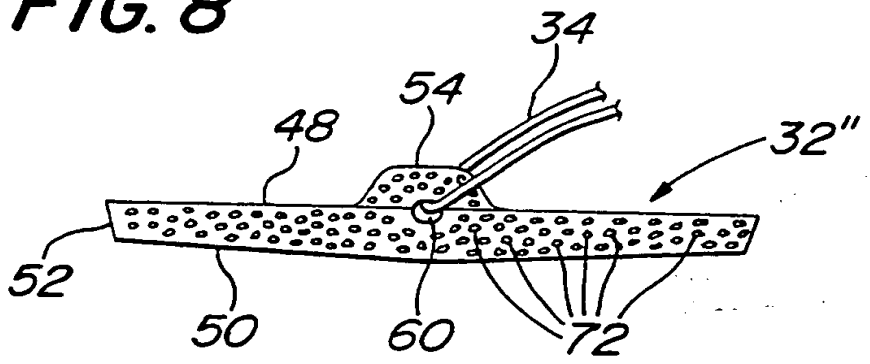


FIG. 9

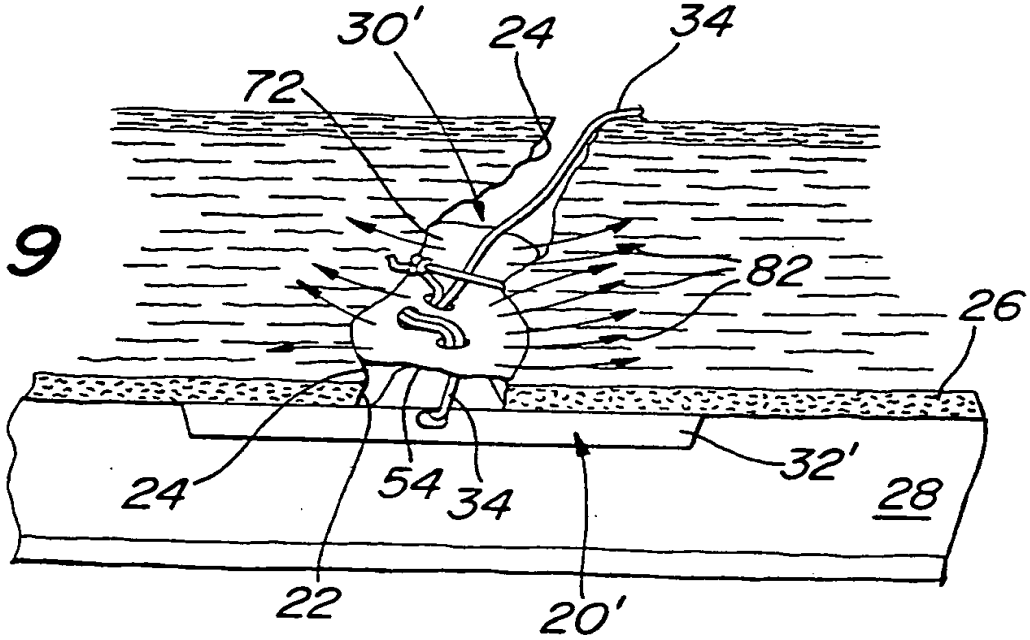
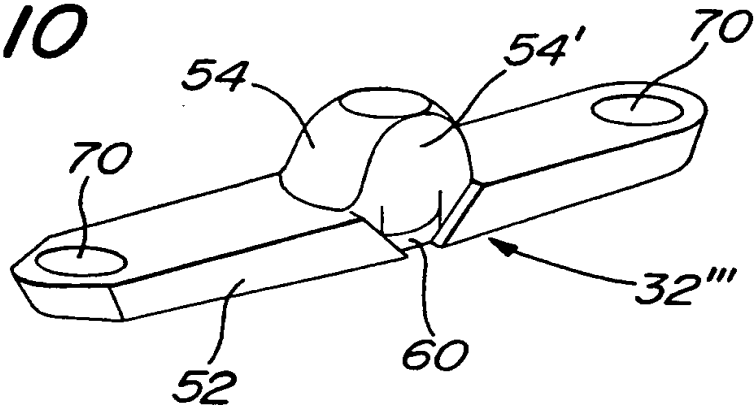


FIG. 10



INTERNATIONAL SEARCH REPORT

Interna · Application No
PCT/US 95/01211

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO,A,90 14796 (MUIJS VAN DE MOER) 13 December 1990 cited in the application	1,2,9
Y	see page 2; figures 6,7	3-8, 10-12
Y	US,A,4 606 337 (ZIMMERMANN) 19 August 1986 cited in the application see column 10, paragraph 2	3-8, 10-12
A	US,A,4 364 392 (STROTHER) 21 December 1982 see column 4, paragraph 2 see column 6, paragraph 2 see column 7, paragraph 1	1,2
A	WO,A,93 08746 (KENSEY NASH) 13 May 1993	
A	EP,A,0 534 696 (ERLEBACHER) 31 March 1993	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 May 1995	19. 05. 95

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Barton, S

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Interna l Application No
PCT/US 95/01211

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A-9014796	13-12-90	NL-A-	8901350	17-12-90
		AU-A-	5823590	07-01-91
		EP-A-	0474752	18-03-92
		JP-T-	4505721	08-10-92
US-A-4606337	19-08-86	DE-A-	3214337	27-10-83
		DE-A-	3378562	05-01-89
		EP-A,B	0092200	26-10-83
		US-A-	4683142	28-07-87
US-A-4364392	21-12-82	NONE		
WO-A-9308746	13-05-93	US-A-	5222974	29-06-93
		US-A-	5282827	01-02-94
		AU-A-	3128993	07-06-93
		JP-T-	6510462	24-11-94
EP-A-534696	31-03-93	CA-A-	2078530	24-03-93
		JP-A-	5212038	24-08-93
		US-A-	5350399	27-09-94

INTERNATIONAL SEARCH REPORT

I national application No.
PCT/US95/01211

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 13-24
because they relate to subject matter not required to be searched by this Authority, namely:
See Rule 39.1 (iv) PCT

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.